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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,961	09/01/2000	Guang-Jer Wu	95-97	5662

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/653,961

Applicant(s)

WU, GUANG-JER

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5,12 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,5,12 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The amendment filed on January 21, 2003 in Paper No. 19 is acknowledged and has been entered. Claims 4, 7-11, and 20 have been canceled. Claims 2, 5, and 12 have been amended. Claim 21 has been added.

2. Claims 2, 5, 12, and 21 are pending in the application and are currently under prosecution.

Grounds of Objection and Rejection Withdrawn

3. Unless specifically reiterated below, the grounds of objection and rejection set forth in the previous Office action has been withdrawn.

For clarity of record, the rejection of the claims under 35 USC § 102(b), which stated the claimed invention is anticipated by Rubenstein, et al (*Prostate* 14: 383-388, 1989), has been withdrawn for the following reason:

Rubenstein, et al teach a method for predicting a subject's risk for a metastasis of prostate cancer consisting essentially of measuring the level of expression of six different tumor-associated markers, whereas the present claims recite a limitation requiring the invention to consist essentially of measuring only a single tumor-associated marker, namely MUC18. The present claims are interpreted to encompass only methods in which the expression of MUC18, and no other tumor-associated marker, is measured.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 2 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu, et al (*Hinyokika Kiyo Acta Urologica Japonica* **39**: 439-444, 1993).

The claims are drawn to a method consisting essentially of measuring the level of expression of MUC18 in a prostate cancer cell with an immunoassay that uses an antibody that binds specifically to an epitope of MUC18.

Liu, et al teach a method consisting essentially of measuring the level of expression of MUC18 in a prostate cancer cell, namely a prostate cancer cell from a biopsy tissue sample from a patient. Liu, et al use an immunoassay to measure the level of expression of MUC18 and an antibody that binds specifically to an epitope of MUC18 in the assay.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. ~~Claims 2, 5, 12, and 21 are rejected under 35 U.S.C. 112, first paragraph, as~~
containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the previous Office action mailed October 2, 2002 (Paper No. 16).

In reply to the previous Office action, Applicant has stated that Applicant traverses this rejection and that the issues raised in the Office action are no longer applicable.

Applicant's remarks have been carefully considered, but Applicant has failed to state the reasons that these grounds of rejection have been traversed. Contrary to Applicant's remarks, the issues raised in the Office action have not been resolved.

8. Claims 2, 5, 12, and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 21 recites, "for predicting a risk for metastasis"; however, there does not appear to be proper and sufficient antecedent basis in the specification to support the recitation of this phrase in the claims. Additionally, there does not appear to be proper and sufficient support for the term "a MUC18 coding sequence" in claim 21, since the disclosure does not refer to more than one sequence encoding MUC18. Accordingly, the recitation of the phrase or term appears to introduce new matter, thereby violating the written description requirement set forth under 35 USC § 112, first paragraph.

In reply to the previous Office action, Applicant has stated that Applicant traverses this rejection and that the issues raised in the Office action are no longer applicable.

Applicant's remarks have been carefully considered, but Applicant has failed to state the reasons that these grounds of rejection have been traversed. Contrary to Applicant's remarks, the issues raised in the Office action have not been resolved.

Still, these matters might be resolved if Applicant were able to point to specific disclosures in the specification that are believed to provide adequate support for the recitation of the phrase or term in the claims.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite because claim 5 recites, "the MUC18 antigen". There is insufficient antecedent basis in claim 21 to support the recitation of this limitation.

Conclusion

11. No claims are allowed.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
April 3, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800